




INSTRUCTIONS FOR ADMINISTRATION (IFA)

JELMYTO® (jel-MYE-toe)

(mitomycin) for pyelocalyceal solution

FOR PYELOCALYCEAL INSTILLATION ONLY

 Read and follow this Instructions for Administration prior to each JELMYTO instillation.

Purpose of this Instructions for Administration

This Instructions for Administration contains information on how to instill JELMYTO using the reconstituted JELMYTO vial which you received from the pharmacy and the devices listed under **Supplies Needed**, obtained by your facility.

Intended Use of JELMYTO

JELMYTO (mitomycin) for pyelocalyceal solution is indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUC).

Important Information You Need to Know Before Instilling JELMYTO

JELMYTO must be reconstituted by a healthcare professional prior to instillation. Reconstituted JELMYTO will appear as a semisolid gel. Once chilled, JELMYTO will convert to a viscous liquid for instillation.

Once instilled into the patient's pyelocalyceal system, JELMYTO will fill and conform to the cavity and become a gel, thereby exposing the tissue to mitomycin over a prolonged period of time.

JELMYTO is viscous, even when it is a liquid in a chilled state. Therefore, you will need a Uroject12 Syringe Lever to instill JELMYTO into the patient. You cannot instill JELMYTO without the Uroject12 device.

Reconstituted JELMYTO should be instilled as soon as possible after reconstitution. Store reconstituted JELMYTO at 20°C to 25°C (68°F to 77°F) for up to 96 hours (4 days). Protect from light.

When ready to instill, chill JELMYTO to 27°F to 41°F (-3°C to 5°C) for at least 10 minutes, but no longer than one hour, to revert it to a liquid form. See the Steps A through E for complete administration instructions.

JELMYTO is a cytotoxic anti-cancer drug. Procedures for Proper Handling and Disposal of anti-cancer drugs should be followed.

This "Instructions for Administration" has been approved by the U.S. Food and Drug Administration.

Distributed by:
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Princeton, NJ 08540
www.JELMYTO.com

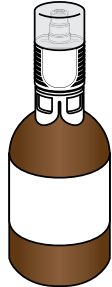
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JEL-IFU-003

Supplies Needed:

One vial of reconstituted JELMYTO, with a resultant concentration of 4 mg of mitomycin per mL following reconstitution.


(prepared and provided by the pharmacy)



JELMYTO vial

Ancillary Supplies:

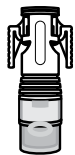
(to be provided by your facility)

 Do not substitute any of these components.

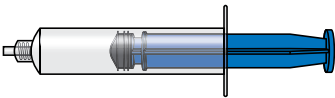
- TEVADAPTOR® Syringe Adaptor or OnGuard®2 CSTD Syringe Adaptor
- MEDALLION® COP or MEDALLION® Luer Lock syringe, 20 mL
- Ureteral Catheter with molded Luer lock port (5 Fr or 7 Fr)
- Uroject12 Syringe Lever

Note: The Uroject12 Syringe Lever is a multi-use device and must be sterilized or disinfected before use. Please follow the sterilization or disinfection instructions detailed in the Uroject12 Syringe Lever Instructions for Use.

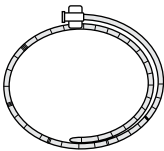
- An ice bath to chill the vial of JELMYTO prior to instillation.



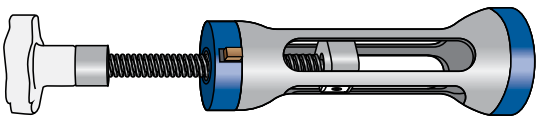
TEVADAPTOR® or OnGuard®2 CSTD Syringe Adaptor



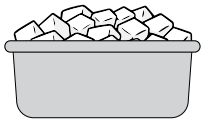
MEDALLION® COP or
MEDALLION® Luer Lock syringe, 20 mL



Ureteral Catheter with molded Luer lock port



Uroject12 Syringe Lever

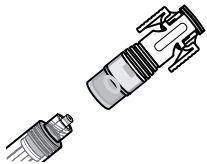


Ice Bath

Frequently Asked Questions:

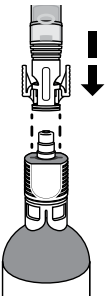
How do I connect the syringe adaptor?

Screw the Luer Lock end of the syringe adaptor onto the syringe hub until it is finger tight.



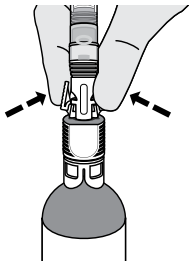
How do I connect the syringe adaptor to the vial adaptor?

Place the syringe adaptor over the vial adaptor and align the tabs; then press down firmly. You will hear a snap which confirms successful attachment.



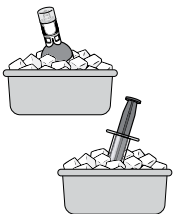
How do I disconnect the syringe adaptor from the vial adaptor?

Pinch the tabs on the syringe adaptor to separate it from the vial adaptor.



I am having a hard time working with reconstituted JELMYTO. It seems to be solidifying.

If you are having difficulty pushing or withdrawing JELMYTO, recap and place the components back into the ice bath until JELMYTO liquifies.

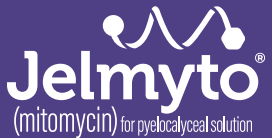
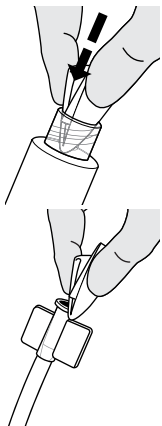


What should I do if there is JELMYTO spillage from the syringe tip?

You will need to clean JELMYTO off the syringe tip and the Luer Lock port of the catheter to ensure the two components can connect securely.

- To clean the syringe tip, fold a sterile gauze pad in half twice, and push it into the inside of the Luer Lock port to wipe any JELMYTO off the threads.
- To clean the Luer Lock port on the catheter, use a sterile gauze pad to wipe off any JELMYTO.

Verify that the connectors are clean to ensure a secure connection between the syringe and the catheter.



Instillation Instructions

A MEASURE THE KIDNEY VOLUME

The Instillation Volume will be equal to the patient's kidney volume. If the kidney volume is already known, proceed to Section B.


If the kidney volume is NOT known, or needs to be reassessed, use the following steps:

- 1 Perform a retrograde pyelogram using diluted contrast (50%) so that the entire renal pelvis and calyces are observed and contrast starts to flow below the ureteropelvic junction (UPJ).
- 2 Record the volume of contrast injected at this point.
- 3 Allow the contrast to drain from the kidney. This may take about five minutes.
Note: Do not withdraw contrast back into the syringe.
- 4 Repeat Steps 1 through 3 two more times, for a total of three measurements to improve accuracy.
- 5 Average the three volume measurements and round to the nearest whole number. This is the patient's kidney volume.

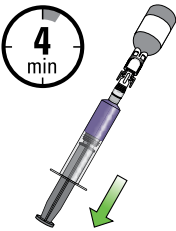
B SELECT THE INSTILLATION VOLUME

- 1 Select the kidney volume OR 15 mL, **whichever is lower**, as the Instillation Volume.
Note: Maximum Instillation Volume is 15 mL. Record this volume for future instillations.

C CHILL THE JELMYTO

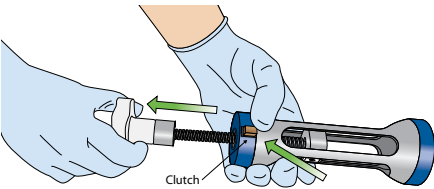
- 1 Place the JELMYTO vial **in the ice bath for at least 10 minutes, but no longer than one hour.** 
- 2 **After at least 10 minutes**, advance the ureteral catheter over the guidewire towards the target anatomy in the pyelocalyceal system.

D PREPARE THE ADMINISTRATION SYRINGE

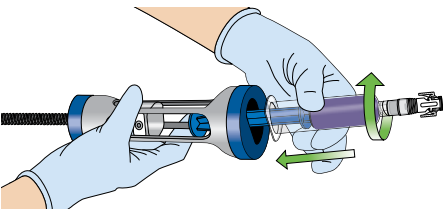
- Once the vial is removed from the ice bath, **you have 4 minutes to draw JELMYTO into the administration syringe** before it solidifies. 
- After 4 minutes, recap and place the components back in the ice bath for no more than 15 minutes to liquify the JELMYTO.

- 1 Remove the JELMYTO vial from the ice bath and dry it off.
- 2 Swirl the vial upright to ensure that JELMYTO is uniformly mixed.
- 3 Connect the syringe adaptor to the 20 mL Luer Lock syringe. This will be the administration syringe.
- 4 Slowly withdraw the calculated Instillation Volume of JELMYTO into the administration syringe.

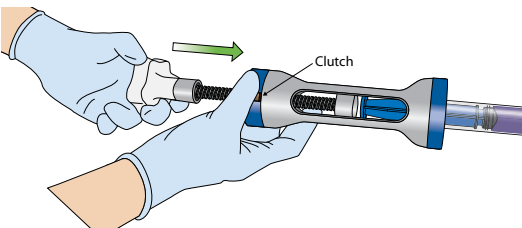
- 5 Press the "Clutch" button on the Uroject12 and pull the knob out.



- 6 Insert the administration syringe into the Uroject12 Syringe Lever and rotate it clockwise until it locks in place.



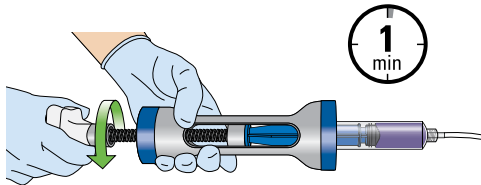
- 7 While pressing the "Clutch" button, advance the lever to just above the administration syringe's plunger.



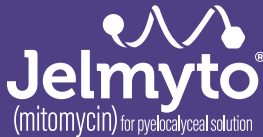
Immediately proceed with the instillation steps in Section E to avoid JELMYTO solidification.

E INSTILL JELMYTO

- 1 Remove the syringe adaptor from the administration syringe.
Note: If JELMYTO gets on to the syringe tip or the catheter's Luer Lock port, wipe it off immediately with sterile gauze so it does not solidify and prevent a secure connection. (Refer to **Frequently Asked Questions** for further details.)
- 2 Connect the administration syringe to the ureteral catheter's Luer Lock port, by rotating the syringe only.
- 3 Using fluoroscopy, ensure the ureteral catheter is in the desired anatomical position.
- 4 Gradually instill the JELMYTO into the patient by turning the knob at a rate of 1-2 seconds per stroke. **The entire syringe must be emptied within one minute.**



- 5 Remove the ureteral catheter from the urinary tract.
- 6 Remove the administration syringe from the Uroject12 by rotating the syringe barrel counter-clockwise.
- 7 Discard the administration ancillaries according to your facility's disposal procedures.
- 8 Send the Uroject12 to be reprocessed according to your facility's procedures and the Uroject12 Syringe Lever Instructions for Use.



Please [click here](#) for Full Prescribing Information for JELMYTO.

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